

Message Text

UNCLASSIFIED

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12

ORIGIN HEW-06

INFO OCT-01 ARA-10 EUR-12 ISO-00 OES-06 /035 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:CCK

APPROVED BY OES/APT/BMP: WJWALSH, III

DHEW/OIH: MACODDING

EUR/NE:JPSHUMATE(INFO)

ARA/CAR:GPALAZZOLO(INFO)

----- 030022

R 180010Z AUG 76

FM SECSTATE WASHDC

TO AMEMBASSY LONDON

AMCONSUL CURACAO

UNCLAS STATE 204937

E.O. 11652: N/A

TAGS: OGEN, ETRD, EIND, TBIO, UK, NA

SUBJECT: FDA ADVISORY - BACTERIAL CONTAMINATION OF
OPHTHALMIC PREPARATION - RECALL D-445-6

1. FDA ADVISES OF THE FOLLOWING RECALL:

PRODUCT INVOLVED:

"EYECOOOL X STERILE X DECONGESTANT X FOR TIRED, ITCHING OR
BURNING RED EYES X 22ML. X DIRECTIONS X CAUTION X INGRED-
IENTS: MENTHOL, OIL, EUCALYPTUS, SODIUM BORIC ACID, SODIUM
CHLORIDE, BORIC ACID, SODIUM BISULPHITE, PHENYLEPHRINE
HYDROCHLORIDE 0.08 PER CENT. PRESERVED WITH THIOMEROSAL
LILLY 0.002 PER CENT - AND EDTA 0.05 PER CENT X MILROY
LABORATORIES DIVISION X MILTON ROY COMPANY X TELLEVAST,
FLORIDA 33588". AN OTC PRODUCT PLACED IN THE EYES.

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PRODUCT IDENTIFICATION:

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M.R. OPHTHALMICS X EYECOOOL X" THERE ARE NO PRIVATE LABELS,

MANUFACTURER LISTED ON LABEL AS FOLLOWS: "MILROY LABORATORIES
DIVISION OF MILTON ROY COMPANY, TELLEVAST, FLORIDA 33588.

LOT NO. INVOLVED - U575

MANUFACTURER/RECALLING FIRM - MILROY LABORATORIES DIVISION
P.O. DRAWER "D"
TELLEVAST, FLORIDA 33588

REASON FOR RECALL - DURING AN ESTABLISHMENT INSPECTION OF
THE FIRM ON APRIL 5, 1976 A SURVEY SAMPLE OF ONE OF THE
FIRM'S STERILE EYE SOLUTION EYECOOOL WAS COLLECTED.
ANALYSIS OF THE SAMPLE REVEALED BACTERIAL CONTAMINATION
WITH PSEUDOMONAS PUTIDA AND VIBRIO EXTORQUENS. THE FIRM
WAS ADVISED OF THE ANALYTICAL FINDINGS BY FDA ON 7/15/76.
THE FIRM ELECTED TO IMMEDIATELY RECALL THE ENTIRE LOT.
ON 7/21/76 RECALL LETTERS WERE MAILED TO ALL CONSIGNEES.

2. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES
TO DETERMINE IF THEY HAVE RECEIVED RECALL LETTER FROM
FIRM DATED 7/21/76 REQUESTING IMMEDIATE RETURN OF LOT NO.
U575 OF EYE COOL. ANY QUESTIONS CONSIGNEES MAY HAVE
REGARDING THIS RECALL SHOULD BE DIRECTED TO THE FIRM.

3. FOREIGN CONSIGNEES AS FOLLOWS:

MR. G. L. WRAY
DUNHILL TOILETERIES LIMITED
DERBY STREET
ORMSTIRK, LANCASHIRE L39 2BX
ENGLAND
INVOICE NO. 682L DATED 2/20/76 10/22 ML BOTTLES

ODUBER AND KAN INCORPORATED, OPTICIANS
P. O. BOX 7, ORANJESTAD
NASSAUSTRAT '2-44
ARUBA, NETHERLANDS ANTILLES
INVOICE NO. 4165 DATED 9/29/75
40/22ML BOTTLES KISSINGER

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01 JAN 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: DRUG CONTROL, INSPECTIONS, PUBLIC HEALTH
Control Number: n/a
Copy: SINGLE
Draft Date: 18 AUG 1976
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1976STATE204937
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, M.D.:CCK
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Film Number: D760316-0571
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1976/newtext/t19760842/aaaabkce.tel
Line Count: 99
Locator: TEXT ON-LINE, ON MICROFILM
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 2
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Review Action: RELEASED, APPROVED
Review Authority: CunninFX
Review Comment: n/a
Review Content Flags:
Review Date: 22 MAR 2004
Review Event:
Review Exemptions: n/a
Review History: RELEASED <22 MAR 2004 by ReddocGW>; APPROVED <24 JAN 2005 by CunninFX>
Review Markings:

Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
04 MAY 2006

Review Media Identifier:
Review Referrals: n/a
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
Secure: OPEN
Status: NATIVE
Subject: FDA ADVISORY - BACTERIAL CONTAMINATION OF OPHTHALMIC PREPARATION - RECALL D-445-6
TAGS: OGEN, ETRD, EIND, TBIO, UK, NA, FDA, MILROY LABORATORIES DIVISION
To: LONDON
CURACAO
Type: TE
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 04 MAY 2006